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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

UNITED STATES OF AMERICA; STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, AND WASHINGTON; THE COMMONWEALTHS OF MASSACHUSETTS AND VIRGINIA; AND THE DISTRICT OF COLUMBIA, ex rel. ZACHARY SILBERSHER,

Plaintiff,

CASE NO. 3:18-cv-3018-JCS

MOTION TO DISMISS AMENDED COMPLAINT BY ADAMAS PHARMA, LLC AND ADAMAS PHARMACEUTICALS, INC.

Judge: Hon. Joseph C. Spero
Date: September 27, 2019
Time: 9:30 a.m.
Courtroom: G, 15th Floor

v.

ALLERGAN PLC, ALLERGAN, INC., ALLERGAN USA, INC., ALLERGAN SALES, LLC, FOREST LABORATORIES HOLDINGS, LTD., ADAMAS PHARMA, LLC, AND ADAMAS PHARMACEUTICALS, INC.,

Defendants.

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NOTICE OF MOTION AND MOTION TO DISMISS

TO ALL PARTIES AND THEIR COUNSEL OF RECORD:

PLEASE TAKE NOTICE that on September 27, 2019, or as soon thereafter as the matter may be heard before the Honorable Joseph C. Spero, in the United States District Court for the Northern District of California, Courtroom G, 15th Floor, United States Courthouse, 450 Golden Gate Avenue, San Francisco, California, Defendants Adamas Pharma, LLC and Adamas Pharmaceuticals, Inc. (collectively, "Adamas") will and hereby do move the Court to dismiss the Amended Complaint pursuant to Federal Rules of Civil Procedure 9(b), 12(b)(1), and 12(b)(6).

This motion is based on this Notice of Motion and Motion to Dismiss; its Memorandum of Points and Authorities; its accompanying Request for Judicial Notice; its accompanying Declaration of Anthony Portelli and related exhibits; any other matters of which the Court may take judicial notice; all other pleadings and papers on file; and the argument of counsel at any hearing on this Motion.

ISSUES TO BE DECIDED

1. Have substantially the same allegations or transactions been publicly disclosed prior to the filing of this *qui tam* action, and, if so, does Relator's repackaging of prior public disclosures qualify him as an original source under to 31 U.S.C. § 3730(e)(4)?
2. Does the Amended Complaint fail to state a claim under the federal False Claims Act and its state law counterparts pursuant to Federal Rules of Civil Procedure 12(b)(6)?
3. Does the Amended Complaint fail to plead the alleged fraud with particularity as required by Federal Rule of Civil Procedure 9(b)?
4. Should the Court dismiss Relator's state law claims for lack of jurisdiction?

MEMORANDUM OF POINTS AND AUTHORITIES

The False Claims Act ("FCA") empowers private whistleblowers with knowledge of fraud to bring lawsuits on behalf of the United States and share up to thirty percent of any government recovery. 31 U.S.C. § 3730. Qualifying as a proper *qui tam* plaintiff, however, takes more than "copying and pasting" content from existing public documents. 31 U.S.C. § 3730(e)(4). This is bad news for Relator Zachary Silbersher, a patent lawyer who moonlights as a serial FCA litigant. Since 2017, Mr. Silbersher has filed at least three *qui tam* actions, including this one, alleging various pharmaceutical companies: (1) procured patents through "fraud" on the U.S. Patent & Trademark Office ("PTO"); (2) enforced these patents to "wrongfully" block generic competition; and (3) caused the government to pay "false" claims for brand-name medications at "artificially high" prices. *See* AC ¶¶ 5-8; Compl., *U.S. ex rel. Silbersher v. Janssen Biotech, Inc.*, No. 17-7250 (N.D. Cal. Dec. 21, 2017); Compl., *U.S. ex rel. Silbersher v. Valeant Pharm. Int'l Inc.*, No. 18-1496 (N.D. Cal. Mar. 8, 2018). But Mr. Silbersher is not a corporate insider, and his complaints do not alert the government to unknown financial fraud. Instead, they regurgitate allegations that have long been in the public domain, without providing any information that is "independent of and materially adds to" prior public disclosures. 31 U.S.C. § 3730(e)(4)(B). Parasitic lawsuits like these are tailor-made for dismissal under the FCA's Public Disclosure Bar.

Mr. Silbersher filed the present action last year. ECF 1. His Amended Complaint, which asserts causes of action under the FCA and twenty-nine state false claims laws, does little more than repeat "inequitable conduct" allegations from previous patent infringement litigation relating to the Alzheimer's medications Namenda XR and Namzaric. *Compare* ECF 7 *with* Declaration of Anthony L. Portelli ("Portelli Decl."), Exs. 1-4.[1] Specifically, the Amended Complaint copies fraud-on-the-PTO allegations from court documents filed in 2014 and 2015, and repackages them as FCA claims based on the "obvious" fact that "monopoly" prices impact government and private payors alike. *See Amphastar Pharmaceuticals, Inc. v. Aventis Pharma S.A.*, 856 F.3d 696, 703 (9th

[1] Under the familiar Rule 12(b)(6) standard, Adamas must accept the Amended Complaint's factual allegations as true for present purposes. However, if this litigation proceeds beyond the motion to dismiss stage, Adamas will vigorously dispute Mr. Silbersher's unfounded allegations and misleading characterizations.

Cir. 2017) (affirming dismissal of *qui tam* complaint premised on alleged inequitable conduct before the PTO, and holding prior allegations "need not include an express reference to the [False Claims Act] for the public disclosure bar to apply"). In fact, Adamas—not Mr. Silbersher—first alerted the United States to these inequitable conduct allegations through documents attached to Information Disclosure Statements ("IDSs") submitted to the PTO in April 2016, more than two years before Mr. Silbersher filed this lawsuit. Portelli Decl., Exs 5 & 6. And every source document cited in the Amended Complaint has been publicly available on the PTO's website, and elsewhere, for many years. Portelli Decl., Exs 7-72. Simply put, Mr. Silbersher wants to get paid for taking information the United States already had, styling it as a "*Qui Tam* Action," and handing it back to the government. But the Public Disclosure Bar precludes "lawsuits in which those with no independent knowledge of fraud use information already available to the government to reap rewards for themselves without exposing any previously unknown fraud." *Seal 1 v. Seal A*, 255 F.3d 1154, 1158 (9th Cir. 2001). This may explain why every federal and state government entity to investigate Mr. Silbersher's allegations has declined to intervene in this action or his copycat lawsuits. ECF 7, 15.

Setting the Public Disclosure Bar aside, the Amended Complaint also fails to plead the essential elements of an FCA violation by Adamas. At the most fundamental level, the complaint fails to identify any "false or fraudulent" claim seeking government payment for Namenda XR or Namzaric. *See* 31 U.S.C. § 3729(a)(1)(A) & (B). Mr. Silbersher instead relies on the implied certification doctrine in an unsuccessful attempt to satisfy the FCA's falsity element. Under that doctrine, failure to disclose noncompliance with a statutory, regulatory, or contractual requirement may give rise to FCA liability, but only if "the defendant *knowingly* violated a requirement that the defendant *knows* is *material* to the Government's payment decision." *Universal Health Servs., Inc. v. U.S ex rel. Escobar*, 136 S. Ct. 1989, 1996 (2016) (emphasis added). The Amended Complaint here falls far short of satisfying the FCA's "demanding" materiality and scienter requirements. *See id*. at 2003. It is deficient under more basic federal pleading standards as well.

Mr. Silbersher's theory is that, starting as early as 2013, Namenda XR and Namzaric claims were "false" because they impliedly certified the federal list prices for these products were "fair

and reasonable," when in fact, those prices were "artificially high." AC ¶ 6. But the Amended Complaint is devoid of *any* facts suggesting *Adamas* provided inaccurate or misleading pricing information, or any other false certification, to the government. To the contrary, the Amended Complaint states Adamas granted Forest Laboratories, Inc. ("Forest")—now part of Allergan—"an exclusive license" to Adamas' intellectual property, which covers Allergan's Namenda XR and Namzaric. AC ¶ 58. The parties executed this license agreement in 2012, years before the submission of any "false" claims alleged by Mr. Silbersher. Under the license agreement, Forest and its successors have been responsible for all "pricing and reimbursement" issues concerning these products since at least 2012, Portelli Decl., Ex. 7, and Mr. Silbersher makes no allegation that Adamas had pricing-related interactions with the government (or anyone else) for these Allergan brands. For this reason, the Amended Complaint fails to plausibly allege Adamas engaged in fraud on federal health care programs, let alone make that allegation "with particularity" as required by Rule 9(b). At best, Mr. Silbersher engages in impermissible group pleading by lumping Adamas among unspecified "Defendants" who allegedly engaged in fraud when selling Namenda XR and Namzaric to the government. *See, e.g., U.S. v. Safran Grp.*, No. 15-00746, 2017 WL 3670792, at *10 (N.D. Cal. Aug. 25, 2017), *aff'd sub nom. Hascoet ex rel. U.S. v. Morpho S.A.*, No. 17-16915, 2019 WL 2213322 (9th Cir. May 22, 2019) ("A relator alleging an FCA claim must provide an adequate factual basis connecting the relator's FCA claim to the particular defendant.").

For all of these reasons, and as explained more fully in this Memorandum, the Court should dismiss the *qui tam* allegations against Adamas in their entirety under Rules 9(b), 12(b)(1), and 12(b)(6). By doing so, the Court would join every other district court to decide a Rule 12 motion seeking dismissal of an FCA complaint premised on alleged fraud-on-the-PTO. *See Amphastar*, 856 F.3d at 705 (rejecting *qui tam* action under Public Disclosure Bar); *U.S. ex rel. Promega Corp. v. Hoffman-La Roche Inc.*, No. 03-1447-A (E.D. Va. Sept. 29, 2004) (rejecting *qui tam* action for failure to state a claim) (Portelli Decl., Ex. 8).

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FACTUAL BACKGROUND

Parties, Products, and Patents. Adamas is a pharmaceutical company focused on development of medicines to treat patients suffering from chronic neurological diseases. The company owns certain patents relating to memantine, an active pharmaceutical ingredient in two Alzheimer's medications—Namenda XR (extended release memantine hydrochloride) and Namzaric (extended release memantine and donepezil hydrochlorides)—that Allergan markets and sells in the United States. AC ¶¶ 58-59. Both of these drugs are at issue in this lawsuit. The U.S. Food & Drug Administration ("FDA") approved Allergan's New Drug Applications ("NDAs") for Namenda XR and Namzaric in June 2010 and December 2014, respectively. AC ¶¶ 51, 55. In turn, Allergan started selling Namenda XR in 2013, and Namzaric in 2015. FDA approval of these products prompted updates to the Agency's "Orange Book," which identifies approved drugs along with related patent and market exclusivity information. AC ¶¶ 57-58; Portelli Decl., Exs. 9-10.

Historically, numerous patents have protected the domestic sale of Namenda XR and Namzaric, including (among others): U.S. Patent No. 8,168, 209, as corrected (the "'209 patent"); U.S. Patent No. 8,173,708 (the '"708 patent"); U.S. Patent No. 8,293,379 (the "'379 patent"); U.S. Patent No. 8,293,794 (the "'794 patent"); U.S. Patent No. 8,362,085 (the "085 patent"); and U.S. Patent No. 8,598,233 (the "'233 patent"). AC ¶¶ 57-58. These six patents are among a group of eleven "Went Patents," all of which are "directed to a formulation that slows down systemic release of memantine compared to immediate release formulations." AC ¶¶ 58-59. Each of the Went Patents names Adamas' founder and Chief Executive Officer, Dr. Gregory T. Went, as the first inventor. AC ¶ 58.

As previously discussed, Adamas granted Forest an exclusive license to the Went Patents under an agreement executed in 2012 ("Agreement"). AC ¶ 58. Adamas has made this Agreement, which the Amended Complaint incorporates by reference, publicly available through previous filings with the U.S. Securities & Exchange Commission ("SEC"). Portelli Decl., Ex. 7. Under the Agreement, Forest has the exclusive right—even as to Adamas and its affiliates—to manufacture, promote, sell, and distribute Namenda XR and Namzaric in the United States. *Id.* ¶¶ 1.18, 2.10(a)(i). The Agreement also grants Forest the right to control all "pricing and

reimbursement" decisions involving these products. *Id.* Mr. Silbersher alleges various Allergan Defendants are the "successor-in-interest" to Forest's rights under the 2012 Agreement, AC ¶ 58, but he does not allege Adamas was involved with pricing or reimbursement issues for Namenda XR or Namzaric, regardless whether government programs or private payors were at issue.

Shortly after FDA approved Namzaric in 2014, the Orange Book was updated to list all eleven Went Patents. AC ¶ 58. In addition, the Orange Book lists U.S. Patent No. 8,039,009 (the "'009 patent") for both Namenda XR and Namzaric. AC ¶ 91. Forest and its successors own the rights to the '009 patent, which is "directed to a method of treating Alzheimer's Disease with a once-daily sustained release oral dose of memantine." AC ¶ 92. As the Amended Complaint makes clear, neither Adamas nor Dr. Went were involved in prosecution of the '009 patent. *See* AC ¶¶ 91-100.

Previous Infringement Litigation. Any manufacturer submitting an application to market a generic product under an Abbreviated New Drug Application ("ANDA") must reference another approved drug and, for each patent listed in the Orange Book for that approved drug, file "a certification, in the opinion of the [ANDA] applicant and to the best of his knowledge, with respect to each patent which claims the listed drug . . . or which claims a use for such listed drug for which the applicant is seeking approval . . . (I) that such patent information has not been filed, (II) that such patent has expired, (III) of the date on which such patent will expire, or (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the [generic] drug for which the [ANDA] is submitted[.]" 21 U.S.C. § 355(j)(2)(A)(vii). When the ANDA applicant certifies that the patent is invalid or not infringed, this is commonly referred to as a "Paragraph IV certification." The Hatch Waxman Act deems Paragraph IV certifications to be acts of infringement, and the patent holder may respond by initiating litigation against the alleged infringer(s). AC ¶ 43. If the patent holder does so within 45 days, this triggers an automatic stay of FDA approval for 30 months from receipt of the Paragraph IV certification or until a district court enters a judgment of non-infringement or invalidity. 21 U.S.C. § 355(j)(5)(B)(iii).

Amneal Pharmaceuticals LLC ("Amneal") was the first of sixteen manufacturers to file an ANDA containing a Paragraph IV certification and seeking FDA approval of a generic version of

Namenda XR. AC ¶¶ 106-107. Each of these generic manufacturers submitted a Paragraph IV certification stating certain patents on Namenda XR were invalid or not infringed. AC ¶ 106. Amneal filed its ANDA in June 2013. AC ¶ 107. In early 2014, certain co-defendants in the present action started filing infringement actions in the U.S. District Court for the District of Delaware. *Id*. These actions asserted six of the Went Patents against all ANDA filers. *Id*. For its part, Amneal responded by filing an Amended Answer, Affirmative Defenses, and Counterclaims ("Amended Answer") in July 2014. Portelli Decl., Ex. 1. This public document alleged "each of the patents in suit, the '209 patent, the '708 patent, the '379 patent, the '794 patent, the '085 patent, and the '233 patent, is unenforceable due to inequitable conduct committed during prosecution by one of the named inventors on each of the patents in suit, Gregory T. Went." *Id*. at 10. Specifically, Amneal alleged Dr. Went submitted three declarations on "unexpected results" to overcome obviousness concerns, and these declarations "contained false and misleading statements concerning the side effect results of the ME110 study," an Adamas-sponsored clinical trial comparing immediate release and extended release formulations of memantine. *Id* at 11-12. According to Amneal, "[e]ach declaration was submitted with an intent to deceive the [PTO] because Dr. Went knew, at the time of filing, that reported side effect results were inaccurate and contradicted the actual results." *Id*.

Amneal's Amended Answer devoted eighteen pages to describing the prosecution histories for the relevant patents, as well as the allegedly "false and misleading" declarations. *Id*. at 10-28. To establish these declarations were knowingly false, Amneal cited to another contemporaneous document—the "May 7 Went Declaration"—which purportedly stated the true results from the ME110 study. *Id*. at 15. Amneal alleged the "same Examiner" at the PTO reviewed both accurate and inaccurate declarations from Dr. Went. *Id*. at 14. Every document referenced in Amneal's Amended Answer—including both the "true" and "false" Went Declarations—has been publicly available to view and download from the PTO's Patent Application Information Retrieval website ("Public PAIR") since at least 2013. Portelli Decl., Exs. 23, 60-71; Attachment A. Public PAIR is a federally maintained database that provides real-time access to issued or published patent

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applications. *See* Public PAIR FAQs *available at* https://www.uspto.gov/patents-application-process/checking-application-status/pair-faqs.

After Amneal filed its Amended Answer alleging inequitable conduct relating to the six Went Patents, only one of the remaining fifteen ANDA filers, Amerigen Pharmaceuticals, Inc. ("Amerigen"), did the same. Portelli Decl., Ex. 2. One year later, when Amneal and Amerigen faced separate infringement actions relating to their ANDAs for generic Namzaric, both companies filed affirmative defenses reiterating their inequitable conduct allegations as to the Went Patents. Portelli Decl., Exs. 3-4. None of the other ANDA filers for Namzaric did so.

In April 2016, Adamas disclosed documents containing the inequitable conduct allegations from the Namenda XR infringement litigation to the PTO via IDSs supporting U.S. Patent Application Nos. 15/090,396 and 15/090,400, which are part of the same family as the Went Patents. Portelli Decl., Exs. 5-6. Those IDSs attached, among other things, the Amneal Amended Answer. *Id*. at 30, #540. Of course, Adamas' transparency with the PTO undercuts any notion that the company or Dr. Went intended to mislead that Office. Regardless, the infringement actions against Amneal and Amerigen settled before any court had an opportunity to adjudicate their inequitable conduct defense. Shortly thereafter, Adamas submitted these settlement agreements to the Antitrust Division of the U.S. Department of Justice ("DOJ") and the U.S. Federal Trade Commission ("FTC"), as required under the Medicare Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066, which entrusts these agencies with responsibility for reviewing brand-generic agreements for potential competition law concerns. Neither DOJ nor FTC has objected to these settlements. However, the Federal Circuit invalidated six of the Went Patents for other reasons in February 2018. AC ¶ 105.

Relator's Complaint. Zachary Silbersher filed this FCA action on May 22, 2018. ECF 1. The FCA imposes liability on any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment" from the United States. 31 U.S.C. § 3729(a)(1)(A). Mr. Silbersher alleges the defendants caused various federal health care programs to receive "false" claims for Namenda XR and Namzaric from 2013 to present. AC ¶ 145. But he does not describe any particular reimbursement claim for these drugs, let alone identify one containing an *expressly*

false statement or certification. Rather, Mr. Silbersher asserts that claims seeking government payment for Namenda XR and Namzaric are *impliedly* false because they fail to disclose the defendants' alleged noncompliance with assorted federal regulations. AC ¶¶ 110-120. With respect to Adamas, Mr. Silbersher alleges the company breached its duty of candor to the PTO when procuring the Went Patents and, because enforcement of those patents "wrongfully" delayed generic competition, Forest and its successors breached a purported obligation to provide "fair and reasonable" pricing for Namenda XR and Namzaric on the Federal Supply Schedule ("FSS"). AC ¶¶ 57-90, 112-113.

As previously discussed, the Amended Complaint does not allege Adamas played any role in procuring the '009 patent. AC ¶¶ 91-102. Moreover, the Adamas/Forest license Agreement, which the Amended Complaint incorporates by reference, AC ¶ 58, makes clear Forest and its successors—not Adamas—have been responsible commercialization of Namenda XR and Namzaric, including all pricing and reimbursement issues for these brands, since at least 2012, well before the submission of any "false" claims alleged by Mr. Silbersher. Portelli Decl., Ex. 7. To the extent the Amended Complaint suggests Adamas was among the "Defendants" that prosecuted the '009 patent or made representations concerning "fair and reasonable" pricing for Namenda XR and Namzaric, this is not only implausible in light the 2012 Agreement, but also impermissible group pleading prohibited by Rule 9(b). Courts must dismiss generalized allegations against "Defendants" that do not "specify what role [a specific defendant]" played in an alleged fraud, and from which the Court cannot discern which entity made false representations to the government. *See Hascoet*, 2019 WL 2213322, at *1.

To allege that Adamas breached a duty of candor to the PTO, the Amended Complaint does little more than copy inequitable conduct allegations that Amneal publicly filed for the first time in 2014. *Compare* ECF 12 *with* Portelli Decl., Ex. 1. Adamas disclosed these very same allegations through documents submitted to the PTO in 2016. Portelli Decl., Exs. 5-6. Attachment A to this Memorandum is a chart placing Amneal's allegations side-by-side with the facts alleged in Mr. Silbersher's operative pleading, as well as numerous publicly available documents containing all of the essential facts underlying Amneal's allegations. The chart demonstrates starkly that the

Amended Complaint repeats Amneal's allegations almost verbatim, without attribution. The Public Disclosure Bar does not abide such plagiarism. Nor should this Court.

Procedural Posture. Mr. Silbersher filed his original complaint under seal pursuant to the FCA's procedural requirements. *See* 31 U.S.C. § 3730. While the complaint was sealed, DOJ investigated Mr. Silbersher's claims. *Id.* § 3730(a). Following DOJ's investigation, the United States declined to intervene in the case. ECF 7. Mr. Silbersher then filed his Amended Complaint, ECF 12, and the States declined to intervene shortly thereafter, ECF 15. The Court unsealed this action on March 28, 2019. ECF 20. Since the federal and state governments completed their investigations, there has been no change to Namenda XR or Namzaric in terms of their eligibility for federal or state reimbursement. The Amended Complaint concedes as much. *See, e.g.*, AC ¶¶ 165 (stating the United States "continues to pay" for Namenda XR and Namzaric following DOJ's investigation) and 175, 187, and 501 (stating each state government also "continues to pay" for these products).

LEGAL STANDARD

Federal Rule of Civil Procedure 12(b)(6) mandates dismissal of complaints that fail to "state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "[L]abels and conclusions" or "formulaic recitation[s] of the elements of a cause of action" are insufficient, as are "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (*quoting Twombly*, 550 U.S. at 545). Because FCA causes of action are fraud-based claims, a *qui tam* plaintiff must plead them "with particularity" under Federal Rule of Civil Procedure 9(b). *See, e.g.*, *U.S. ex rel. Cafasso v. Gen. Dynamics C4 Sys., Inc.*, 637 F.3d 1047, 1055 (9th Cir. 2011); *Ebeid ex rel. U.S. v. Lungwitz*, 616 F.3d 993, 998-99 (9th Cir. 2010). To satisfy Rule 9(b), the relator must identify the "who, what, when, where, and how" of the fraud, *Ebeid*, 616 F.3d at 998, including "what is false or misleading about a statement, and why it is false." *U.S. v. United Healthcare Ins. Co.*, 848 F.3d 1161, 1180 (9th Cir. 2016). In reviewing the sufficiency of the complaint, courts may consider the contents of the pleading and its attached exhibits, documents incorporated into the complaint by reference, and matters properly subject to judicial notice. *Tellabs, Inc. v. Makor Issues & Rights,*

Ltd., 551 U.S. 308, 322-23 (2007). While courts grant leave to amend "freely," Fed. R. Civ. P. 15(a)(2), amendment is inappropriate when the plaintiff cannot cure the complaint's defects by alleging additional facts. *Lopez v. Smith*, 203 F.3d 1122, 1127 (9th Cir. 2000).

ARGUMENT

I. THE PUBLIC DISCLOSURE BAR PRECLUDES RELATOR'S LAWSUIT AGAINST ADAMAS.

A relator may not base an FCA action or claim on previously disclosed allegations or transactions, unless the relator qualifies as an "original source" of the information. 31 U.S.C. § 3730(e)(4). The Public Disclosure Bar advances the twin purposes of the FCA: "to alert the government as early as possible to fraud that is being committed against it" and "to encourage insiders to come forward with such information where they would otherwise have little incentive to do so." *U.S. ex rel. Biddle v. Bd. of Trustees of Leland Stanford, Jr. Univ.*, 161 F.3d 533, 538 (9th Cir. 1998). If the government is already "on notice" of the fraud alleged in a *qui tam* complaint, or the relator lacks insider knowledge, the Public Disclosure Bar applies. *U.S. ex rel. Fryberger v. Kiewit Pacific Co.*, 41 F. Supp. 3d 796, 803 (N.D. Cal. 2014) (dismissing *qui tam* complaint because "prior public disclosures contained enough information to enable the government to pursue an investigation" of the defendant). The bar discourages "parasitic lawsuits" by non-insiders who rely on public information and fail to shine a light on any previously unknown fraud. *Seal 1*, 255 F.3d at 1158; *U.S. ex rel. JDJ & Assoc., LLP v. Natixis*, 15-5427, 2017 WL 4357797 (S.D.N.Y. Sept. 29, 2017) ("The FCA bars 'parasitic lawsuits' based upon publicly disclosed information in which would-be relators 'seek remuneration although they contributed nothing to the exposure of the fraud.'") (*quoting United States ex rel. Kreindler & Kreindler v. United Techs. Corp.*, 985 F.2d 1148, 1157 (2d Cir. 1993)).

"Parasitic lawsuits" are Mr. Silbersher's business model, and the Amended Complaint is a paragon example. The government was "on notice" of every allegation and transaction concerning Adamas years before Mr. Silbersher filed this action, and he has no "insider" knowledge to offer. *See Fryberger*, 41 F. Supp. 3d at 802. These facts are fatal to Mr. Silbersher's lawsuit.

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A. The Amended Complaint Repackages Prior Public Disclosures.

Under the FCA, public disclosure occurs when "substantially the same allegations or transactions" alleged in a *qui tam* action were communicated previously "(i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party; (ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or (iii) from the news media." 31 U.S.C. § 3730(e)(4)(A). The Ninth Circuit has defined "allegations" to mean "direct claims of fraud," while "transactions" are "facts from which fraud can be inferred." *Amphastar*, 856 F.3d. at 703 (*quoting U.S. ex rel. Mateski v. v. Raytheon Co.*, 816 F.3d 565, 570 (9th Cir. 2016)). A prior disclosure "need not contain every specific detail" later alleged in *qui tam* complaint for the bar to apply. *Amphastar*, 856 F.3d at 703. Instead, it is sufficient for the prior disclosure to include a "critical mass" of the underlying facts or allegations later pleaded in a *qui tam* lawsuit. *Id*. Courts may take judicial notice of materials to determine whether a qualifying public disclosure has occurred. *See, e.g., U.S. ex rel. Hong v. Newport Sensors, Inc.*, 728 F. App'x 660, 661 (9th Cir. 2018) ("The district court did not abuse its discretion in taking judicial notice of the seven documents that [defendant] submitted to demonstrate public disclosure."); *U.S. ex rel. Ambrosecchia v. Paddock Labs., LLC*, 855 F.3d 949, 954 (8th Cir. 2017) ("In evaluating whether the public disclosure bar applies, we may 'consider matters incorporated by reference or integral to the claim, items subject to judicial notice, [and] matters of public record.'") (*quoting U.S. ex rel. Paulos v. Stryker Corp.*, 762 F.3d 688, 696 (8th Cir. 2014)).

In the present action, both its allegations against Adamas, and the essential facts underlying those allegations, were a matter of public record long before Mr. Silbersher filed this lawsuit. Defendants in previous litigation made the same "direct claims of fraud" against Adamas as far back as 2014. *Amphastar*, 856 F.3d. at 703. Adamas, in turn, disclosed documents containing those allegations to the United States, during patent application proceedings before the PTO. And the "facts from which fraud can be inferred" were in the government's possession and publicly available long before Mr. Silbersher became a professional *qui tam* plaintiff and brought this action in 2018. *See id.*

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1. *Relator copied his inequitable conduct allegations from previous public filings.*

The "fraud" alleged by Mr. Silbersher and the "inequitable conduct" alleged by Amneal (and later by Amerigen) are virtually identical. Attachment A to this Memorandum juxtaposes these allegations, as they appear in court documents, and establishes that far more than a "critical mass" of Mr. Silbersher's allegations were publicly disclosed before he sued Adamas. *See Amphastar*, 856 F.3d at 703. For example, both Mr. Silbersher and Amneal have alleged:

- Dr. Went overcame an initial rejection for the '209 patent by submitting a "false and misleading" declaration to the PTO dated November 5, 2010 (the "Original Went Declaration"). *Compare* AC ¶¶ 62-63, 67 *with* Portelli Decl., Ex. 1 at 11-14.
- The Original Went Declaration misrepresented certain side effect results from the ME110 study. *Compare* AC ¶¶ 66-67 *with* Portelli Decl., Ex. 1 at 13.
- Dr. Went knew his Original Declaration was false, and submitted another declaration (the "May 7 Went Declaration") containing the true results of the ME110 study in connection with a different patent application. *Compare* AC ¶ 68 *with* Portelli Decl., Ex. 1 at 15.
- The PTO relied on the Original Went Declaration when issuing the '708 patent. *Compare* AC ¶ 75 *with* Portelli Decl., Ex. 1 at 23.
- Dr. Went submitted the Original Went Declaration and another "false" declaration (the "Corrected Went Declaration") in the process of procuring the '379 patent. *Compare* AC ¶ 76 *with* Portelli Decl., Ex. 1 at 41.
- Like the Original Went Declaration, the Corrected Went Declaration also misrepresented results from the ME110 study. *Compare* AC ¶ 77 *with* Portelli Decl., Ex. 1 at 41-43.
- During successful prosecution of the remaining Went Patents—including the '794 patent, the '085 patent, and the '233 patent—Dr. Went submitted another declaration that misrepresented ME110's results ("the "Third Went Declaration"). *Compare* AC ¶ 80 *with* Portelli Decl., Ex. 1 at 45.
- "Defendants" caused FDA to list the "unenforceable" Went Patents in the Orange Book for Namenda XR and Namzaric, and thereby frustrated lower-cost generic alternatives from entering the market. *Compare* AC ¶ 57 *with* Portelli Decl., Ex. 1 at 31.

At bottom, there is only one difference between the fraudulent schemes alleged by Amneal/Amerigen and Mr. Silbersher: the latter makes the unremarkable observation that market exclusivity impacts prices for government programs, just as it does for private payors. The Ninth Circuit has considered precisely this issue and decided such distinctions are no barrier to the Public

Disclosure Bar. *Amphastar*, 856 F.3d at 704 (holding inequitable conduct allegations from prior infringement litigation triggered the bar because "[t]he only new allegation [relator] makes in the instant case is that the government also bought the drug while [defendant] held its illegal monopoly, but this is an obvious inference based on the publicly disclosed allegations").

Because prior fraud allegations are "substantially the same" as those contained in the Amended Complaint, and because Adamas disclosed documents containing those prior allegations to the PTO years before Mr. Silbersher filed suit, the Public Disclosure Bar applies to the present action. 31 U.S.C. § 3730(e)(4).; *Seal 1*, 255 F.3d at 1158 (holding purpose of public disclosure bar is to discourage non-insiders from using "information already available to the government to reap rewards for themselves without exposing any previously unknown fraud"). The PTO is an agency of the U.S. Department of Commerce, and it is legally required to publish prosecution histories as an official, formal statement of federal proceedings. 37 C.F.R. § 1.211. Accordingly, documents generated by the PTO, as well as IDSs and other materials submitted to the PTO by patent applicants, are "Federal reports" for purposes of the FCA. *See* 31 U.S.C. § 3730(e)(4)(A)(ii). The U.S. Supreme Court interprets "report" in a manner "consistent with the generally broad scope of the FCA's public disclosure bar." *Schindler Elevator, Corp. v. U.S. ex rel. Kirk*, 131 S. Ct. 1885, 1891 (2011) (defining "report" under the FCA as "something that gives information," a "notification," or an "official or formal statement of facts or proceedings") (internal citations omitted). In *Schindler Elevator*, the Supreme Court held "[a] written agency response to a FOIA [Freedom of Information Act] request falls within the ordinary meaning of 'report'" for purposes of the FCA, even though the agency in question only made its FOIA response available to the specific requestor, not the general public. *Id*. at 1983. Lower courts have applied *Schindler Elevator* to find documents submitted to a federal agency qualify as "Federal reports" as well. *See, e.g., U.S. ex rel. Ryan v. Endo Pharmaceuticals, Inc.*, 27 F. Supp. 3d 615, (E.D. Pa. 2014) (holding a "10–k filing [with the SEC] qualifies as a public disclosure as a federal report").

2. *The United States was on notice of every key transaction before Relator filed suit.*

The Public Disclosure Bar would preclude Mr. Silbersher's complaint even if Amneal and Amerigen had never alleged inequitable conduct back in 2014, and even if Adamas had not

submitted IDSs attaching the Amneal and Amerigen allegations back in 2016. Under the statute, the "bar is raised so long as the material elements of the allegedly fraudulent 'transaction' are disclosed in the public domain." *A–1 Ambulance Service, Inc. v. California*, 202 F.3d 1238, 1243 (9th Cir. 2000). This does not require "an explicit 'allegation' of fraud" in the prior disclosures. *Mateski*, 816 F.3d at 571 (quoting *Hagood v. Sonoma Cty. Water Agency*, 81 F.3d 1465, 1473 (9th Cir. 1996)). The Ninth Circuit uses the "X + Y = Z" test to analyze whether a "transaction" has been publicly disclosed:

> In order to disclose the fraudulent transaction publicly, the combination of X and Y must be revealed, from which readers or listeners may infer Z, i.e., the conclusion that fraud has been committed . . . . In a fraud case, X and Y inevitably stand for but two elements: a misrepresented state of facts and a true state of facts. In order to invoke the . . . bar, a defendant must show 'that the transaction . . . is one in which a set of misrepresented facts has been submitted to the government.'"

U.S. ex rel. Hong v. Newport Sensors, Inc., No. 13-1164, 2016 WL 8929246, at *5 (C.D. Cal. May 19, 2016) (*quoting Mateski*, 816 F.3d at 571).

Here the "misrepresented state of facts" [X] are false and misleading statements that Adamas allegedly made to the PTO regarding the incidence of certain side effects in the ME110 study, and the "true state of facts" [Y] are the actual results of the ME110 study. *See Newport Sensors, Inc.*, 2016 WL 8929246, at *5. Per the Amended Complaint, Dr. Went allegedly provided the United States with the "X" via declarations submitted to the PTO on November 5, 2010, April 2, 2012, and June 25, 2012. AC ¶¶ 63, 77, 80. And he provided the PTO with the alleged "Y" through a separate declaration dated May 7, 2012. AC ¶ 69. By combining the alleged "X" and the alleged "Y," a reader may infer "Z"— namely, that the alleged "fraud has been committed." *See Newport Sensors, Inc.*, No. 13-1164, 2016 WL 8929246, at *5. This is precisely what Amneal and Amerigen did back in 2014, and Mr. Silbersher has done the same many years later. *See* AC ¶¶ 68-69 (concluding "Dr. Went knew that his summary of the ME110 Study . . . was false" because of the "contrast" between the Went Declarations dated November 5, 2010 and May 7, 2012).

For this reason, the prosecution histories for the Went Patents, and the Went Declarations themselves, contain the "material elements" of the allegedly fraudulent transactions later repeated

by Mr. Silbersher. *See A–1 Ambulance Service*, 202 F.3d at 1243. Adamas submitted these Declarations to the PTO between seven and nine years ago in connection with various patent applications specifically referenced in the Amended Complaint. AC ¶¶ 58-81. The relevant prosecution histories, including all four Went Declarations, have been available for viewing and inspection on Public PAIR—the PTO's electronic database of patents, patent applications, prosecution histories, and related records—since at least 2013. Portelli Decl., Exs. 23, 60-71. The Public PAIR website does not require login credentials, and it is easily searchable by patent number and application number. The Went Declarations and other patent prosecution documents are public disclosures because they are posted on Public PAIR, which qualifies as a "Federal report" under the FCA. *See* 31 U.S.C. § 3730(e)(4)(A)(ii); *U.S. ex rel. Rosner v. W.B./Stellar IP Owner, LLP*, 739 F. Supp. 2d 396, 405-07 (S.D.N.Y. 2010) (holding publicly-searchable database on government agency's website was a "report" under the Public Disclosure Bar). Public PAIR also qualifies as "news media." *See id*. § 3730(e)(4)(A)(iii); *Newport Sensors*, 2016 WL 8929246, at *5 ("Information publicly available on the Internet generally qualifies as 'news media.'").

B. Relator Is Not An Original Source.

A relator may avoid the Public Disclosure Bar if he or she is an "original source," which means someone who either "prior to a public disclosure . . . has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based" or "has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing" a *qui tam* lawsuit. 31 U.S.C. § 3730(e)(4)(B). Mr. Silbersher does not qualify. He is not an insider, whistleblower, or former employee of defendants; he has not alleged that his disclosure to the government pre-dates any of the prior public disclosures outlined in Section I.A. of this Memorandum; nor has he pled any facts beyond a boilerplate recitation of the statutory elements that his "knowledge" is "independent" and "materially adds to any publicly disclosed allegations." *See* AC ¶¶ 10, 22. Such boilerplate recitations are not enough. *U.S. v. Kimberly-Clark Corp.*, No. 14-8313, 2017 WL 10439690, at *8 (C.D. Cal. Nov. 30, 2017) (dismissing *qui tam* complaint under

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the Public Disclosure Bar because allegation that "simply parrots the standard for determining an original source without providing any factual basis for the claim" was inadequate).

At most, Mr. Silbersher tries to sneak under the Public Disclosure Bar by applying his expertise as a patent litigator to facts previously disclosed; however, merely using one's own expertise "to conclude that the material elements already in the public domain constitute a false claim" neither qualifies one as an "original source" nor survives the bar. *A-1 Ambulance Serv.*, 202 F.3d at 1245; *U.S.A. ex rel. Calva v. Impac Secured Assets Corp.*, No. 16-1983, 2018 WL 6016152, at *8 (C.D. Cal. June 12, 2018) ("simply conducting a specialized analysis of publicly available information based on his expertise does not make him an 'original source.'"); *U.S. ex rel. Casady v. Am. Int'l Grp., Inc.*, No. 10-0431, 2013 WL 1702777, at *4 (S.D. Cal. Apr. 19, 2013) ("Relators cannot escape the public disclosure bar by basing a fraud claim" on "their analysis" of "government and public documents").

Mr. Silbersher did not and cannot plead facts sufficient to show he is an original source. Instead, he repackaged allegations and transactions from the public record—information already in the possession of the United States—in the hopes of personal profit. As a non-insider, Mr. Silbersher lacks the "independent" and "material" new information that might otherwise allow him to sidestep the Public Disclosure Bar. *See Amphastar*, 856 F.3d at 705 ("To prove 'independent knowledge' relators have to show they had relevant evidence of fraud prior to the public disclosure."); *Malhotra v. Steinberg*, 770 F.3d 853, 860 (9th Cir. 2014) (requiring relators "to show that they knew of the information underlying the . . . allegations before" the public disclosure). For this reason, any further amendment here would be futile, and the Court should dismiss this lawsuit without leave to amend. *See Lopez*, 203 F.3d at 1127.

II. THE AMENDED COMPLAINT FAILS TO STATE A FALSE CLAIMS VIOLATION AGAINST ADAMAS.

To state a claim under the FCA, Mr. Silbersher must allege "(1) a false statement or fraudulent course of conduct, (2) made with scienter, (3) that was material, causing (4) the government to pay out money or forfeit moneys due." *U.S. ex rel. Rose v. Stephens Inst.*, 909 F.3d 1012, 1017 (9th Cir. 2018), *cert. denied sub nom. Stephens Inst. v. U.S. ex rel. Rose*, 139 S. Ct.

1464 (2019). He must plead each of these elements "with plausibility and particularity under [Rule] 9(b)" to survive a motion to dismiss. *Escobar*, 136 S. Ct. at 2004 n.6. He has failed to do so.

A. Relator Fails To Plead a False Claim.

Mr. Silbersher's allegations of misrepresentations to the PTO—in connection with patent proceedings—and the General Services Administration ("GSA")—in connection with the FSS—do not establish FCA liability because Mr. Silbersher fails to plead a "false or fraudulent" claim for government payment. 31 U.S.C. § 3729(b)(2) (defining "claim" as "any request or demand, whether under contract or otherwise, for money or property") For purposes of the FCA, a claim may be factually or legally false. A factually false claim misrepresents the services or goods provided to the government. *See U.S. ex rel. Mateski v. Raytheon Co.*, No. 06-03614, 2017 WL 3326452, at *4 (C.D. Cal. Aug. 3, 2017), *aff'd*, 745 F. App'x 49 (9th Cir. 2018). A legally false claim falsely certifies, either expressly or impliedly, compliance with material laws, rules, or regulations. *See Rose*, 909 F.3d at 1017. Express false certification "means that the entity seeking payment certifies compliance with a law, rule or regulation as part of the process through which the claim for payment is submitted," whereas implied false certification means an entity seeking payment "has previously undertaken to expressly comply with a law, rule, or regulation, and that obligation is implicated by submitting a claim for payment." *Ebeid*, 616 F.3d at 998.

Here, Mr. Silbersher uses conclusory phrases, such as "express and implied assurances," AC ¶ 6, "express and implied misrepresentations," AC ¶ 117, and "express or implied certifications," AC ¶ 120, against unspecified defendants, in an attempt to survive dismissal, but he fails to state an actual "false" claim to the government by any defendant.

1. *Relator fails to allege Adamas caused factually false claims.*

Mr. Silbersher does not and cannot assert that Adamas made or caused factually false claims for Namenda XR or Namzaric. Adamas was not involved in pricing or reimbursement for these products and, furthermore, Mr. Silbersher does not allege that the government received Namenda XR or Namzaric at anything other than the quality, amount, and price agreed. Moreover, none of the alleged misrepresentations to the PTO concerning the Went Patents—the only misrepresentations alleged in the Amended Complaint with respect to Adamas—were themselves

claims for payment, 31 U.S.C. § 3729(b)(2), and thus none can create liability for a factually false claim. Similarly, while Adamas played no role in submitting information to the GSA in connection with the FSS, any such submissions are not themselves a claim for payment, and cannot give rise to a factual false claims violation. Mr. Silbersher thus does not allege Adamas submitted or caused any claim that was "literally false or fraudulent" as required to plead a factually false claim. *U.S. ex rel. Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1170 (9th Cir. 2006).

2. *Relator fails to allege Adamas caused legally false claims.*

The Amended Complaint fails to identify any expressly false certification of compliance that Adamas caused to be made in connection with a claim seeking reimbursement from federal health care programs for Namenda XR or Namzaric. Rather than plead the submission of any express false certification, Mr. Silbersher alleges Adamas violated a duty of candor to the PTO, which in turn led other parties to violate GSA's "fair and reasonable" pricing requirement. AC ¶¶ 110-112, 117. However, Mr. Silbersher's allegations fail because there is no nexus between the GSA's determination that a price is "fair and reasonable" and any purported inequitable conduct before the PTO.

As a threshold matter, the GSA's "fair and reasonable" determination is not the catch-all regulatory obligation that Mr. Silbersher alleges. Indeed, drug companies seeking to list their products on the FSS are *not* required to make any certifications about the fairness or reasonableness of the prices they offer. Instead, drug makers merely provide certain objective pricing data and metrics for assessment by the GSA. According to one GSA document cited in the Amended Complaint, AC ¶ 114, the GSA's review process is designed to "ensure . . . the Government is receiving a fair and reasonable price," but the agency's assessment is limited to "comparing the prices/discounts that a company offers the government with the prices/discounts offered to commercial customers." Portelli Decl., Ex. 74 at CP-11 & CP-8. This is why the GSA only requires manufacturers to supply objective information such as the offered product's price, most-favored customer information, and tracking customer information. *See* AC ¶ 112. But Mr. Silbersher is not alleging Adamas or any other defendant submitted incorrect commercial pricing data, misrepresented tracking customer information, or made other incorrect or inaccurate statements to

the GSA. Nor does Mr. Silbersher plead that the agreed-upon Namenda XR and Namzaric discounts were anything but fair and reasonable in comparison with the accurate commercial pricing data supplied to the government. And Mr. Silbersher cites no authority—because he cannot—holding that a drug's patent prosecution history and the PTO's reasons for issuing a patent are in any way relevant to the GSA's "fair and reasonable" pricing determination.

At most, Silbersher offers an attenuated theory of FCA liability that reimbursement claims for Namenda XR and Namzaric were legally "false" because they contained impliedly false certifications of compliance with (1) the GSA's "fair and reasonable" pricing requirement, and/or (2) Adamas' duty of candor to the PTO. To plead an implied certification claim, a relator must allege two conditions: "first, [that] the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, the defendant's failure to disclose noncompliance with *material* statutory, regulatory, or contractual requirements makes those representations misleading half-truths." *Escobar*, 136 S. Ct. at 2001 (emphasis added); *see also Rose*, 909 F.3d at 1018. Here, Mr. Silbersher fails to plead facts satisfying either condition.

The Amended Complaint fails to allege that any reimbursement claim "makes specific representations about the goods . . . provided." *Id.* In fact, Mr. Silbersher fails to identify any claim seeking government payment for Namenda XR and Namzaric, let alone describe specific contents of any such claim that might be rendered "misleading half-truths" through nondisclosure of previous regulatory violations. *See Escobar*, 136 S. Ct. at 2001; *U.S. ex rel. Kelly v. Serco, Inc.*, 846 F.3d 325, 332 (9th Cir. 2017) (FCA claim failed "as a matter of law" when relator offered no evidence that alleged false claim "made any specific representations"). Mr. Silbersher's failure to connect his allegations concerning misrepresentations to the PTO and GSA to "specific representations" in an actual claim for government payment is fatal to his FCA claim. *Ebeid*, 616 F.3d at 1000 (general allegations of a failure to comply without facts setting out the "who, what, when, where, and how . . . is not enough" to plead an implied certification claim).

B. Relator Fails To Plead Materiality.

Even if the Amended Complaint satisfied the "specific representations" prong of the *Escobar* test (it does not), Mr. Silbersher fails to satisfy the "material" noncompliance prong.

Under the implied certification doctrine, "a misrepresentation about compliance with a statutory, regulatory, or contractual requirement" may be actionable under the FCA when failure to disclose the violation would be "material to the Government's payment decision." *Escobar*, 136 S. Ct. at 2002. The FCA's materiality standard is "demanding" and not "too fact intensive" to decide on a motion to dismiss. *Id.* at 2003, 2004 n.6. "[M]ateriality looks to the effect on the *likely* or *actual* behavior of the recipient of the alleged misrepresentation" and requires specific facts showing that the Government's payment decision would likely or actually have been different had the Government known about the alleged regulatory violations. *Id.* at 2002 (emphasis added).

Here, Mr. Silbersher alleges only that compliance with the duty of candor before the PTO, as well as the GSA's "fair and reasonable" pricing "requirement," were "*per se* material to the government's payment decision" for Namenda XR and Namzaric. AC ¶ 117. *Escobar* and its progeny reject this "*per se*" theory of materiality. *See Knudsen v. Spring Commc'ns Co.*, 2016 WL 4548924 at *13 (N.D. Cal. Sept. 1, 2016) (holding that a "single, conclusory paragraph" alleging that certain "terms were *per se* material to the government's decision to contract with Defendants" was insufficient to plead materiality under *Escobar*, which has "rejected a theory of materiality that any statutory, regulatory, or contractual violation is material just because it can result in the government's decision not to pay a claim").

In addition, Mr. Silbersher fails to plead facts showing that the "fraud" he alleges would "likely" or "actually" cause the government to refuse payment for Namenda XR and Namzaric. *See Escobar*, 136 S. Ct. at 2001. Mr. Silbersher pleads on "information and belief" that the government "would not have entered into" contracts to pay for Namenda XR and Namzaric had it "known the true facts at the time of contracting or payment." AC ¶ 156. These conclusory statements are inadequate, and the government's actions seem to cut the other way. Since February 2018, when the Federal Circuit ruled certain of the Went Patents invalid, there has been no change to the FDA approval status of Namenda XR or Namzaric, nor has there been any change to these products in terms of their eligibility for government reimbursement, as Mr. Silbersher himself concedes. *See, e.g.*, AC ¶ 165 (stating the government "continues to pay" for Namenda XR and Namzaric as of January 22, 2019).

Even more damning to Mr. Silbersher's FCA claim, there can be no dispute that his complaint notified the government about his legal theory, including defendants' alleged fraud-on-the-PTO and related misrepresentations to the GSA, and the United States had an obligation to investigate his allegations "diligently," 31 U.S.C. §3730(a). Yet the government declined to intervene in this lawsuit without taking any further action to limit federal or state reimbursement of Namenda XR and Namzaric. This further reinforces the insufficiency of Mr. Silbersher's implied certification claim because "if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated," that is "very strong evidence that those requirements are not material." *Escobar*, 136 S. Ct. at 2003-04. Courts routinely reject FCA claims where the government was aware of the relator's allegations, investigated them, and continued to pay anyway.[2]

Lastly, Mr. Silbersher has not and cannot assert that "the Government consistently refuses to pay claims in the mine run of cases based on noncompliance" with PTO or GSA regulations. *See Escobar*, 136 S. Ct. at 2003. At least one court has already rejected an analogous effort to impose FCA liability through alleged fraud-on-the-PTO. In *United States ex rel. Promega Corp. v. Hoffman-La Roche Inc.*, No. 03-1447-A (E.D. Va. Sept. 24, 2004), the relator alleged that the defendants had "fraudulently obtained" patents by lying to the PTO, that "years later Defendants

[2] *See, e.g.*, *D'Agostino v. ev3, Inc.*, 845 F.3d 1, 7 (1st Cir. 2016) (affirming dismissal of *qui tam* complaint because, "[t]he fact that CMS has not denied reimbursement for Onyx [a medical device] in the wake of D'Agostino's allegations casts serious doubt on the materiality of the fraudulent representations that D'Agostino alleges."); *Coyne v. Amgen, Inc.*, No 17-1522, 2017 WL 6459267, at *3 (2d Cir. Dec. 18, 2017) (affirming dismissal of a *qui tam* complaint because the Government "did not alter its reimbursement practices" after learning of alleged misrepresentations); *U.S. ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 490 (3rd Cir. 2017) (affirming dismissal of *qui tam* complaint because, "[s]imply put, a misrepresentation is not 'material to the Government's payment decision,' when the relator concedes that the Government would have paid the claims with full knowledge of the alleged noncompliance."); *U.S. ex rel. McBride v. Halliburton Co.*, 848 F.3d 1027, 1034 (D.C. Cir. 2017) ("[W]e have the benefit of hindsight and should not ignore what actually occurred: the [Government] investigated McBride's allegations and did not disallow any charged costs. . . . This is 'very strong evidence' that the requirements allegedly violated . . . are not material."); *United States ex rel. Berg v. Honeywell Int'l, Inc.*, 740 F. App'x 535, 538 (9th Cir. 2018), *cert. denied sub nom. U.S. ex rel. Berg v. Honeywell Int'l, Inc.*, 139 S. Ct. 1456 (2019) (holding relators "failed to raise a triable issue as to the element of materiality on the 'demanding' standard established in *Escobar* and *Kelly*" because Army continued paying contractor's claims for several years despite being aware of relators' fraud allegations, the results of its own audit, and problems with the infiltration rates used by contractor).

used those patents to obtain contracts with the Government," and that "every invoice submitted for payment under these contracts" therefore constituted an FCA violation. *Id.* at 5. The *Promega* court dismissed this FCA claim as "fatally flawed," holding that the alleged "misrepresentations to the USPTO from years ago" could not amount to a false claim because of their "disconnect" from "the invoices submitted to the Government." *Id.* Adamas is not aware of any federal court decision holding that fraud-on-the-PTO is a proper predicate for a *qui tam* action.

C. Relator Fails To Plead Scienter.

In general, false claims are actionable only if a defendant "knew that its statements were false, or that it was deliberately indifferent to or acted with reckless disregard of the truth of the statements." *U.S. ex rel. Lee v. Corinthian Colls.*, 655 F.3d 984, 996 (9th Cir. 2011). And in an implied certification case like this one, "[w]hat matters is . . . whether the defendant *knowingly* violated a requirement that the defendant *knows* is material to the Government's payment decision." *Escobar*, 136 S. Ct. at 1996 (emphasis added). Mr. Silbersher makes no such allegation against Adamas. At most, Mr. Silbersher provides barebones, conclusory statements that Adamas and Dr. Went "knowingly" made misrepresentations to the PTO, AC ¶¶ 2, 3, 5, even though the Amended Complaint itself shows that Dr. Went actively corrected past statements to the PTO on multiple occasions. On top of this, the Amended Complaint lacks any allegation that Adamas or Dr. Went knowingly violated their regulatory obligations, or that Adamas or Dr. Went knew those regulations were material to government payment decisions. *See Escobar*, 136 S. Ct. at 1996. Accordingly, Mr. Silbersher again fails to plead an essential element of an FCA case.

III. THE COURT SHOULD DISMISS RELATOR'S STATE LAW CAUSES OF ACTION.

Like Mr. Silbersher's federal claim, his state claims also fail, and the Court should dismiss them. 28 of the 29 state statutes invoked in the Amended Complaint have provisions highly similar to the FCA's public disclosure rule, with several of these state provisions containing true jurisdictional bars. *See* ECF 63 at 23, App. B. Beyond this, the substantive prohibitions of the relevant state false claims laws are modeled closely on the FCA, to which courts look for guidance. *See e.g., U.S. v. Somnia, Inc.*, 339 F. Supp. 3d 947, 954 (E.D. Cal. 2018) ("state courts turn to federal FCA case law for guidance in interpreting" state false claims laws). Accordingly, Adamas'

arguments against Mr. Silbersher's FCA claim apply with equal force to his state law claims, all of which are subject to dismissal under Rules 9(b), 12(b)(1), and/or 12(b)(6). Regardless, if the Court dismisses Mr. Silbersher's federal claims, it should decline to exercise supplemental jurisdiction over the state law claims. *See* 28 U.S.C. § 1367(c)(3) ("The district courts may decline to exercise supplemental jurisdiction over a claim . . . if . . . the district court has dismissed all claims over which it has original jurisdiction."); *Les Shockley Racing, Inc. v. Nat'l Hot Rod Ass'n*, 509 884 F.2d 504, 509 (9th Cir. 1989) ("When, as here, the court dismisses the federal claim leaving only state claims for resolution, the court should decline jurisdiction over the state claims and dismiss them.").

CONCLUSION

For the reasons stated in the Memorandum, the Court should dismiss Mr. Silbersher's Amended Complaint, without leave to amend.

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